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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510-337-6700
FAX: 510-337-6702

WARNING LETTER

July 20, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MQSA Facility ID: 123430
Inspection ID: 1234300007
FDA Reference #: 2951759

Richard Gross, M.D.
Medical Director
Roseville Imaging Center
Radiological Associates
1130 Conroy Lane, Suite 100
Roseville, California 95661

Dear Dr. Gross:

We are writing to you because on June 24, 1998, your facility was inspected by Ms. Mindy Malone, a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography practices at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

1. The interpreting physicians did not meet the requirement of being licensed by a State to practice medicine: [redacted] and [redacted]. {21CFR§900.12(a)(1)(i)}

2. The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms: [redacted]. {21CFR§900.12(a)(1)(ii)(A)(B)}

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions

include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of forty patient examinations per month over twenty-four months: [redacted] {21CFR§900.12(a)(1)(iv)(A)}

2. The interpreting physicians did not meet the continuing education requirements of having completed a minimum of fifteen credits in mammography over a three year period (an average of five credits/year): [redacted] and [redacted] {21CFR§900.12(a)(1)(iv)(B)}

3. The interpreting physician did not meet the initial training requirement of having forty hours of continuing medical education in mammography: [redacted] {21CFR§900.12(a)(1)(ii)(C)}

4. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in six months: [redacted] {21CFR§900.12(a)(1)(iii)(A)}

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter: (a) the specific steps you have taken to correct all of the violations noted in this letter; (b) each step your facility is taking to prevent the recurrence of similar violations; (c) equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and (d) sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records **(Note: Patient names or identification should be deleted from any copies submitted).**

Please submit your response to:

Mr. John M. Doucette
MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
TEL: 510-337-6793
FAX: 510-337-6702

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please contact Mr. John M. Doucette at 510-337-6793.

Sincerely yours,

Charles D. Moss
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District Office

cc: Trisha Edgerton, Chief, Mammography Accreditation
Mindy Malone, MQSA Inspector (2184)
State of California
Department of Health Services
Radiologic Health Branch
P.O. Box 942732
601 N. 7th Street, MS-178
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cc: Dawn Gonzales, Director of Diagnostic Operations
Radiological Associates of Sacramento
1800 I Street
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